


BMJ Open Impact of allergic rhinitis on the day-to-day lives of children: insights from an Australian cross-sectional study

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To cite: Bosnic-Anticevich S, Smith P, Abramson M, *et al.* Impact of allergic rhinitis on the day-to-day lives of children: insights from an Australian cross-sectional study. *BMJ Open* 2020;**10**:e038870. doi:10.1136/bmjopen-2020-038870

► Prepublication history and additional material for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-038870>).

Received 27 March 2020

Revised 31 August 2020

Accepted 25 September 2020

ABSTRACT

Study design and objective Cross-sectional, observational survey to describe the impact of allergic rhinitis (AR) on Australian children (2 to 15 years).

Methods Participants (n=1541), parents of children aged 2 to 15 years, provided information on behalf of themselves and one eligible child in their household using a custom-built online questionnaire. Children were allocated to case (AR) or control (No AR) analysis groups based on a validated screening questionnaire.

Statistical methods The study sample was stratified on age: primary analysis population (6 to 15 years, n=1111; AR=797, No AR=314); exploratory population (2 to 5 years). The primary endpoint, parent-perceived burden, was quantified using a validated measure of health status and analysed via comparison of means.

Results The majority of AR cases were treated (730/797; 90.3%) and classified as having moderate-severe, intermittent AR (549/797; 68.9%). Half reported adequate symptom control in the prior 2 weeks (389/797; 48.8%; OR=4.04; 95% CI (CI) 2.24 to 7.31). Having AR was associated with worse overall health status (7.4 vs 8.4, mean difference (least squares mean difference (LSMD))=−0.99; 95% CI −1.18 to −0.79), fewer days being happy (22.2 vs 25.9, LSMD=−3.68; 95% CI −4.82 to −2.54) and more days of poor physical (2.82 vs 0.78, LSMD=2.04; 95% CI 1.61 to 2.47) and emotional (2.14 vs 0.67, LSMD=1.47; 95% CI 1.02 to −1.92) health compared with not having AR. All of these outcomes were significantly (p<0.05) worse in children who reported inadequate symptom control. Having AR negatively impacted on schoolwork, sleep and other activities, and increased the likelihood of having comorbidities.

Conclusion The parent-perceived burden of AR in Australian children is high and it impacts many areas of day-to-day living. Inadequate symptom control is a key driver of the extent of this impact. Opportunities to optimise the management of AR in children include the adoption of self-assessment tools to gauge and monitor adequacy of symptom control.

INTRODUCTION

Allergic rhinitis (AR), an IgE-mediated, chronic inflammatory disorder affecting the nasal mucosa, is characterised by episodes of repeated sneezing, rhinorrhoea and nasal congestion, often accompanied by itching of

Strengths and limitations of this study

- This study used objective measures to quantify the negative impact of paediatric allergic rhinitis on health status, emotional well-being, physical health, school and sleep.
- All data were parent-reported and were collected using a customised online survey questionnaire, which included relevant validated tools.
- The International Study of Asthma and Allergies in Childhood questionnaire provided the basis for screening participants and was used to allocate children to case or control groups for analysis.
- The data revealed some interesting findings, notably the significant role of adequacy of symptom control, and raised questions about the level of parental knowledge regarding the medication their child is taking.
- The validity of the data was limited due to methodological constraints, including online sampling, inability to verify sample representativeness and collection of parent-reported data rather than those of the child directly.

the eyes, nose and palate.¹ Pharmacological treatment aims to achieve symptom control, but current Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines suggest the need to take account of multiple factors beyond efficacy, speed of onset and safety when selecting pharmacotherapy for patients to encompass patient preferences, symptom severity, prior treatments, self-management strategies and the effects of AR on sleep and work productivity.² This reflects an increasing recognition that the interlinked concepts of disease severity and control are complex in AR. Rather than equating severity directly with physiological function, patients with AR tend to equate severity with the negative impact that the allergies have on their lives.³ Understanding what drives this negative impact of AR is important; and is further heightened where treatments for this condition are available in the pharmacy setting where patients often self-select.



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Health-related quality of life (HR-QoL) is a complex and multidimensional concept used as a marker of disease impact beyond clinical impact, morbidity or mortality. It is often used to capture subjective perceptions and objective assessment of a patient's health and well-being.⁴ HR-QoL in children with AR is an important and emerging area of interest, primarily due to the fact that the impact of AR on the day-to-day lives of individuals can be felt beyond the severity of symptoms experienced. In their review of 27 studies of children with AR, aged 10 to 19 years, Blaiss *et al*⁵ highlighted the negative impact of AR on several aspects of day-to-day living including: daily functioning, sleep, absenteeism, school productivity and academic performance. Adolescents with AR have high rates of somatisation, anxiety and depression, less resistance to stressful situations, and exhibit more hostility, impulsivity and rapid changes in interest. Parental assessment of the impact of AR on the day-to-day lives of children with AR indicates that AR makes their child unhappy, upset, angry and embarrassed.⁶ In practical terms, HR-QoL can be used to describe the way in which health status affects quality of life.⁷ Some of the most important research exploring the impact of AR on the day-to-day lives of children in the USA have used the concept of 'health status' as a means of determining the burden of AR.⁸ It is in recognition of this research, and the high prevalence of AR, that we focus on AR in children.

Previous Australian data reported a prevalence of AR of approximately 12.9% in children aged 6 to 7 years and 19.3% in children aged 13 to 14 years.⁹ More recent data suggest a higher, and rising,¹⁰ prevalence: 15.1% to 37.8% in adolescents aged 12 to 15 years in Europe¹¹ and 24.8% among children aged 14 to 17 years in the USA.¹² Data from an Australian longitudinal birth cohort study (Perth Infant Asthma Follow-up (PIAF) study) demonstrated a rapid increase in the development of AR over childhood (7% at age 6 years, 18% at age 11 years and increasing to 24% by age 18 years).¹³ However, despite this high prevalence, published Australian data on the impact and management of AR in children are minimal and outdated.¹⁴

To address this gap, we conducted a national, online survey to generate contemporary data describing the burden of AR on the day-to-day lives of Australian children (2 to 15 years), with the aim of identifying gaps and opportunities for optimising care in the future. Inherent difficulties in properly identifying AR in young children (2 to 5 years) were addressed by the study sample being stratified on age with the primary analysis population encompassing children 6 to 15 years and an exploratory population encompassing the younger children (2 to 5 years). We report here the primary study results.

METHODS

The survey was conducted between 15 October 2018 and 12 November 2018. The study sample was derived from three ISO-accredited research-only panels of respondents

for online consumer research in Australia (Ipsos i-Say 180 000 members, Research Now/Survey Sampling International 400 000 members and Pure Profile 250 000 members). Panel members completed a series of screening questions, including inclusion and exclusion criteria, and eligible respondents provided informed consent prior to accessing the survey. Eligible participants were aged 21 years or over, currently residing in Australia and the parent/guardian of at least one child aged 2 to 15 years. Participants provided information on behalf of themselves and one eligible child in their household. Participants with multiple eligible children were randomly allocated a specific child on which to answer questions.

Data collection and cohort description

All data were parent-reported, and collected using a customised online survey questionnaire, which was self-administered once. The questionnaire (online supplemental file 1) comprised a series of closed-answer questions, incorporating relevant validated tools and other questions developed empirically through review of the AR literature and other health surveys.

The questionnaire explored 11 domains: (1) screening (International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire),¹⁵ (2) family medical history, (3) parent-perceived burden (as assessed by the validated single health status question,¹⁶ and the validated Healthy Days questionnaire¹⁷ and impact of AR on day-to-day living (adapted from Pediatric Allergies in America Survey)),¹⁸ (4) beliefs about medicines (Beliefs about Medicines questionnaire),¹⁹ (5) knowledge and beliefs about allergies (knowledge, attitude and practice questions in AR and asthma),^{20–22} (6) AR classification (ARIA criteria),^{1,23} (7) AR diagnosis, (8) AR triggers and testing, (9) AR symptoms (Contre les Maladies Chroniques pour un Vieillessement Actif (MACVIA)-ARIA validated visual analogue scales (VAS)^{3,24,25}), (10) symptom control (Control of Allergic Rhinitis and Asthma Test for Children)²⁶ and (11) AR management strategies. The length of the questionnaire was a key consideration; to minimise bias resulting from questionnaire fatigue, data collected about the survey respondents (parents/guardians) were minimal, with the majority of data relating to the specified child on whose behalf the questionnaire was being completed.

The ISAAC questionnaire¹⁵ provided the basis for screening participants and was used to allocate respondents' children to case or control groups for analysis. Cases (AR) were defined as children with symptoms of AR that were not associated with a cold/influenza, and controls (No AR) were defined as children without symptoms of AR. Within the AR group, a subgroup was defined based on information provided that the child was currently using an allergy medication, where 'treated AR' had selected one or more types of medicines from a list, while those allocated to 'untreated AR' had selected either 'none' or 'don't know'.

Burden of AR was determined based on four questions: a single validated question, 'In general, how would you describe your child's health?' to provide a measure of health status, and three questions to assess the number of healthy days per month, as reflected in the number of the number of days in the last month the child could be described as being (a) healthy (happy and full of energy), (b) had poor physical health or (c) had poor emotional health. These four questions were derived from the validated Centers for Disease Control and Prevention (CDC) Healthy Days Core Module¹⁷ and the Pediatric Allergies in America Survey.¹⁸ The original, validated, health status question was answered using a 5-point Likert scale (excellent, very good, good, fair or poor).¹⁷ To provide a quantitative value for statistical analyses, it was administered using a 10 cm VAS (0= poor; 10= excellent). To determine the impact of AR on day-to-day living, questions used in the Pediatric Allergies in America Survey¹⁸ were modified in order to capture data relating to performance at school and in other activities, sleep duration, sleep quality, absenteeism and presenteeism. Taking into consideration the lower target age of the children in the survey was 2 years, for pragmatic reasons the questionnaire was answered by an adult on behalf of the child, hence all findings are reported as being parent-perceived.

Patient and public involvement

The research question and outcomes measures were informed by the results of prior published research in paediatric AR patients. However, at the time of protocol development, a review had identified a number of important data gaps, noting few recent data on the impact of AR in adolescents and questioned the relevance of available evaluations of HR-QoL in the current social landscape.⁵ Patients were not involved in the design of the survey questionnaire, the conduct of the study or reporting of the results.

Sample size

The primary endpoint was parent-perceived burden (health status) in children aged 6 to 15 years in case (AR) versus control groups (no AR). It was determined that the study would require a sample of at least 1000 children for univariate logistic regression and 1100 children for multivariable logistic regression, assuming the sample was children aged 6 to 15 years, with an expected symptom prevalence of 4% (4.45%,²⁷ an OR of 1.5 (1.5 among children aged 6 to 17 years⁵), an alpha of 5% (95% CI), a power of 80% and a 30% multiple correlation with other covariates. To allow for the exploratory analysis in young children, the sample was extended proportionately to the age range 2 to 5 to maintain the same power. Sample selection quotas were stratified based on the child's age, gender, geographical location and meeting case/control criteria. Children meeting case criteria were also stratified based on AR classification, management and management type.

Statistical analysis

Variables included prevalence, family history, parent-perceived burden^{16 17} and impact,¹⁸ symptoms, diagnosis, triggers and management. Baseline demographic variables (child's age and gender) were used as criteria to test for differences. All information was summarised using descriptive statistics for continuous data and frequency tables for categorical data. Summaries were provided based on relevant analysis samples: controls (No AR), all cases (AR), AR cases treated and AR cases not treated. Observations with missing values were excluded and answers of 'Don't Know' were replaced with missing values.

Data were analysed using the χ^2 test for two-way tables and by binary logistic or multinomial models for variables with more than two levels. All statistical analyses were performed at the 5% significance level using two-sided tests or two-sided CIs. For two-way tables, OR with 95% CI and p values were created to quantify any associations. Additional analyses were conducted to understand the relationships, multi-level associations and interactions and control for potentially confounding factors. The analysis was built progressively through phases, by first understanding the univariate relationships (for continuous variables) or associations (for categorical variables), and then incorporating analysis and modelling which brought in more than one variable to account for interactions or potentially confounding factors. The variables incorporated in the secondary modelling included variables identified in the initial analysis with a cut-off of $p < 0.05$.

The level of parent-perceived burden was determined via comparison of means, 95% CI for the means and their differences and t or z tests for the following groups: cases (AR) versus controls (No AR), cases (AR) treated versus not treated, and cases (AR) with good versus poor symptom control. Where there were more than two groups, analysis of variance was applied to test for a significant difference between groups. Depending on the group, analyses conducted were: distribution and comparison of means (least squares means (LSM)), generalised linear models (GLM), contingency tables and OR, and GLM model with interactions. This analysis was applied to each of the four questions used to determine burden: health status, the number of healthy days in the last 30 days and the number of unhealthy days in the last 30 days (a combined mean of physically unhealthy days and emotionally unhealthy days).¹⁷ Covariates identified based on the outcome of the baseline variables analyses were then included as independent variables along with group allocation (AR or No AR) and treatment type in multiple linear regression of the above mean parent-perceived burden measures. Summaries and statistical analyses were generated using Q-research software (V.5.3.2, Displayr, Chicago, Illinois) and SAS (V.9.4, SAS Institute, Cary, North Carolina).

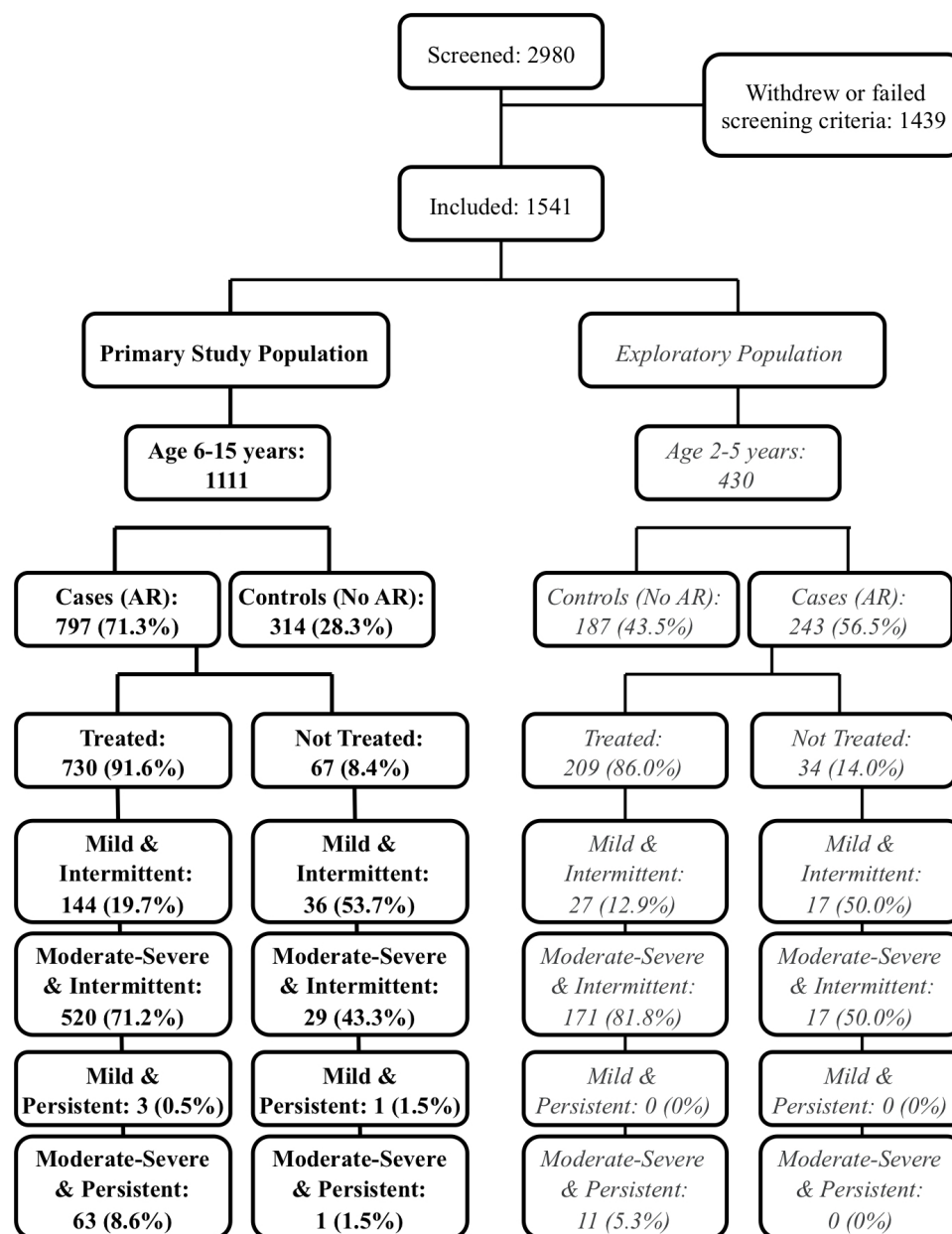


Figure 1 STROBE flowchart of participants, group allocation: AR/No AR based on the International Study of Asthma and Allergies in Childhood questionnaire;¹⁵ mild/moderate-severe and intermittent/persistent based on the Allergic Rhinitis and its Impact on Asthma Criteria;¹²³ and treated/not-treated based on parental report of current allergy medicine use. AR, allergic rhinitis.

RESULTS

Of the 2980 potential participants screened, 1541 met the inclusion criteria and completed the survey. Approximately two-thirds of respondent were female and their mean age was 42 years (online supplemental table 1). The primary analysis sample comprised 1111 children, aged 6 to 15 years (figure 1); the majority of AR cases were being treated (730/797; 90.3%) and were classified as having moderate-severe, intermittent AR based on the ARIA criteria (549/797; 68.9%).

Demographics

There was no statistically significant difference between the mean ages of AR case and control children. Children

treated for AR, were older than those not treated (11.5 vs 10.1 years, 95% CI -2.12 to -0.53). Parental AR was associated with significantly increased odds of AR in their offspring (OR 5.21, 95% CI 3.78 to 7.18) and there were statistically significant relationships between having AR and sinusitis, asthma, cough, recurrent wheezing, hives, nasal polyps or food allergy. Children with AR were significantly more likely to have undergone ear, nose and throat procedures than those without AR (table 1). In the past 12 months, doctor visits were reported significantly more frequently in children with AR than those without (3.2 vs 1.4 visits, $p<0.001$). After hay fever, the three most common reasons for seeking a doctor's advice in children

Table 1 Medical history and doctor visits. Data presented as N (%)

Medical procedures	Cases (AR) n=797	Controls (No AR) n=314	Cases (AR) treated n=730	Cases (AR) not treated n=67
Tonsils removed	127 (15.9%)*	19 (6.1%)	118 (16.2%)	9 (13.4%)
Adenoids removed	104 (13.0%)*	19 (6.1%)	98 (13.4%)*	6 (9.0%)
Tubes put in his/her ears	69 (8.7%)*	12 (3.8%)	67 (9.2%)*	2 (3.0%)
Nasal or sinus surgery	63 (7.9%)*	3 (1.0%)	59 (8.1%)	4 (6.0%)
Required braces for their teeth	195 (24.5%)*	50 (15.9%)	182 (24.9%)*	13 (19.4%)
None of the above	446 (56.0%)	240 (76.4%)*	400 (54.8%)	46 (68.7%)*
Reasons for visits to the doctor	Cases (AR) n=729 [†]	Controls (No AR) n=190 [†]	Cases (AR) treated n=672 [†]	Cases (AR) not treated n=57 [†]
Asthma	38 (18.9%)*	18 (9.5%)	127 (18.9%)	11 (19.3%)
Sinusitis	84 (11.5%)*	3 (1.6%)	81 (12.1%)	3 (5.3%)
Hay fever/AR (nasal and/or eye allergy symptoms)	324 (44.4%)*	1 (0.5%)	311 (46.3%)*	13 (22.8%)
Sleep disturbances	45 (6.2%)*	2 (1.1%)	42 (6.3%)	3 (5.3%)
Adenoids/tonsils hypertrophy	50 (6.9%)*	2 (1.1%)	48 (7.1%)	2 (3.5%)
Eczema (atopic dermatitis)	72 (9.9%)*	6 (3.2%)	67 (10.0%)	5 (8.8%)
Vaccinations	121 (16.6%)*	17 (8.9%)	116 (17.3%)*	5 (8.8%)
Cough	322 (44.2%)*	62 (32.6%)	295 (43.9%)	27 (47.4%)
Nasal polyps	26 (3.6%)*	1 (0.5%)	26 (3.9%)*	0 (0.0%)
Hives (urticaria)	21 (2.9%)*	1 (0.5%)	20 (3.0%)	1 (1.8%)
Respiratory tract infection	139 (19.1%)*	18 (9.5%)	134 (19.9%)*	5 (8.8%)
Urinary tract infection	24 (3.3%)	4 (2.1%)	20 (3.0%)	4 (7.0%)
Acne	39 (5.3%)	5 (2.6%)	37 (5.5%)	2 (3.5%)
Other	183 (25.1%)	114 (60.0%)*	161 (24.0%)	22 (38.6%)*

*Statistically significant difference between groups (cases versus controls; cases treated versus not treated) at 95% CI. The list of reasons was prespecified in the survey questionnaire.

[†]Sample size smaller than the total population due to missing data.
AR, allergic rhinitis.

with AR were cough, respiratory tract infections and asthma, all of which were significantly higher than in children without AR (table 1).

AR symptoms and adequacy of control

The average age at symptom onset was 6.7 years (treated AR) and 6.2 years (untreated AR). Parents of children with AR reported that runny nose, nasal congestion, itchy eyes and repeated sneezing were the four most bothersome symptoms (online supplemental table 2). When the level of bother from each symptom was reported using a 10 cm VAS, facial pain, difficulty getting to sleep, disturbed sleep, distractibility and irritability were the most frequently reported moderate-severely bothersome symptoms (figure 2).

Overall, half of the children with AR were reported to have adequate symptom control (VAS score of ≤ 5 on a 10 cm scale) over the past 2 weeks (389/797; 48.8%). The majority of children currently treating their AR were using tablets/liquids (453/730, 62%), half were using nasal sprays (365/730, 50%) and one in three were using eye drops (211/730, 29%). The majority of children who

were treating their AR had been advised to do so by a healthcare professional (general practitioner: 372/730 (51%), pharmacist: 175/730 (24%) and specialist: 80/730 (11%)). However 10% (73/730) of children were being managed based on the decisions of their parents.

Irrespective of the medication class, the majority of children began using their medication either at the onset of symptoms or the onset of the allergy season (online supplemental table 3). Over one-third of children (263/730, 36%) who had been identified as treating their AR had taken medication on the day of the survey. The mean bother score was higher in these children (6.14 ± 2.04) than in those who had not taken their medication that day (3.20 ± 2.68).

Burden and impact of AR

Based on the single validated question, 'In general how would you describe your child's health?' to determine health status, children with AR had significantly higher parent-perceived burden than did those without AR (figure 3). Subgroup analyses showed that these differences remained statistically significant for comparisons of

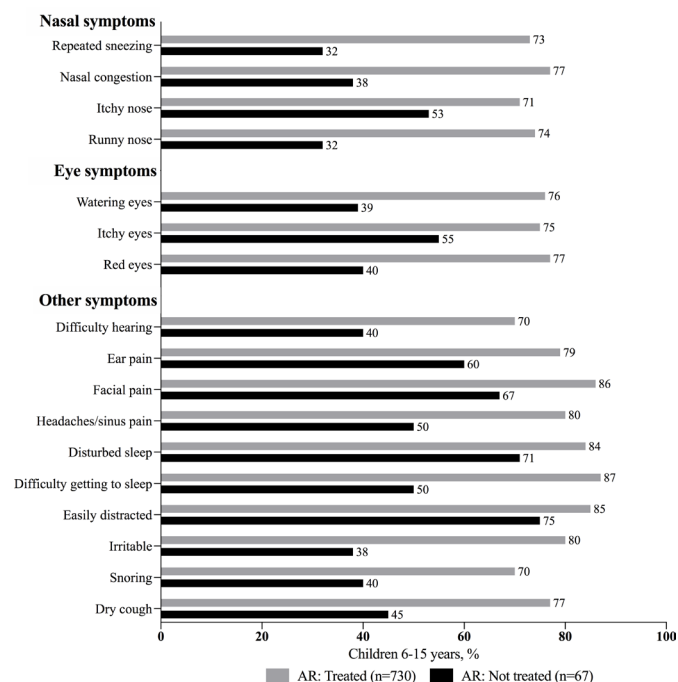


Figure 2 Proportion of children with AR in whom symptoms were moderate-severely bothersome*. *Defined as a score between 6 and 10 on a 10 cm visual analogue scale (0 cm= not at all bothersome and 10 cm= extremely bothersome (as bad as they can get)).³⁴ AR, allergic rhinitis.

children with inadequate symptom control versus good symptom control and of children with moderate-severe versus mild AR, but not for treated versus untreated cases (figure 3). Having AR, poor symptom control and moderate-to-severe disease were also associated with fewer

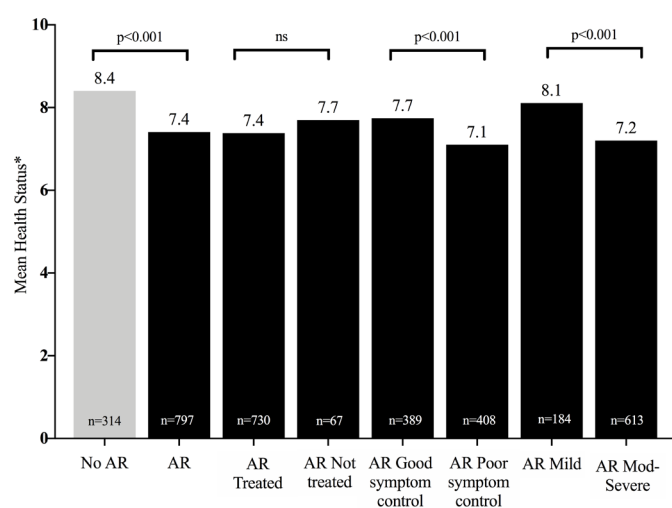


Figure 3 Parent-perceived burden: health status in children aged 6 to 15 years. *Health status was based on the single question, 'In general, how would you describe your child's health?',^{16 18} adapted to be answered on a 10 cm VAS (0= poor health and 10= good health). Mean score was derived from the cut-off criteria: VAS<2= very poor; 2≤VAS<4= poor; 4≤VAS<6= good; 6≤VAS<8= very good and 8≤VAS≤10= excellent). AR, allergic rhinitis; ns, not significant; VAS, visual analogue scale.

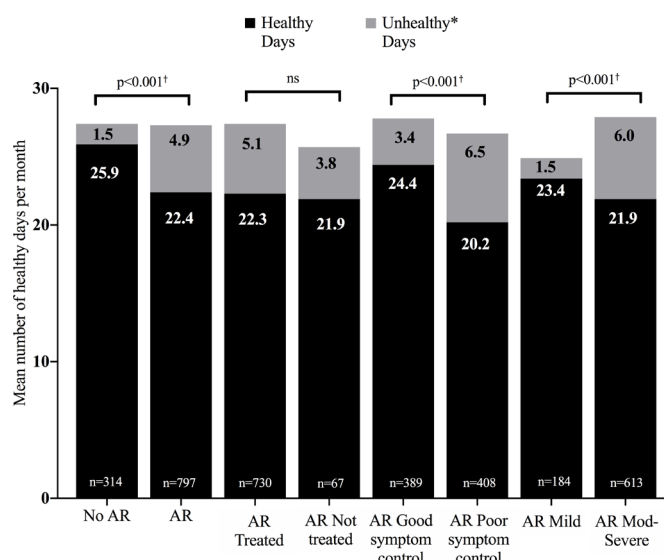


Figure 4 Parent-perceived burden: healthy and unhealthy days per month in children aged 6 to 15 years. The number of days in the last month the child was either healthy (happy and full of energy), had poor physical health or had poor emotional health were measured based on questions derived from the Centers for Disease Control and Prevention's Healthy Days Core Module¹⁷ and the Pediatric Allergies in America Survey.¹⁸ *Unhealthy days= number of days of poor emotional health and number of days of poor physical health combined. †Statistically significant difference between groups for each metric (healthy days and unhealthy days). AR, allergic rhinitis.

healthy days and more unhealthy days (poor emotional and physical health) per month (figure 4). There was a significant association between AR classification, treatment and adequacy of symptom control (figure 5). Based on health status, parent-perceived burden was least in untreated children who had mild AR and good symptom control (LSM health score: 8.24; 95% CI 7.68 to 8.80) and greatest in untreated children who had moderate-severe AR and inadequate symptom control (LSM health score: 6.58; 95% CI 5.72 to 7.44).

The burden of AR was greatest in children with co-morbidities (figure 6A). Parent-perceived burden was lowest in children with AR who also had other conditions (LSM 7.27; 95% CI 7.07 to 7.47), but was not significantly lower than in children with AR and no other conditions (LSM 7.47; 95% CI 7.32 to 7.62). Parent-perceived burden was significantly lower in children with AR, either with or without comorbidities, than in those without AR with (LSM 8.03; 95% CI 7.78 to 8.53) or without (LSM 8.58; 95% CI 8.38 to 8.78) comorbidities. This trend was also seen in the number of healthy days (figure 6B), days of poor physical health and days of poor emotional health per month (figure 6C).

Having AR versus not having it was associated with significantly reduced ability to perform schoolwork and other activities. Children accomplished less than they would usually have done at school or in other activities, and a reduced level of care was taken when performing

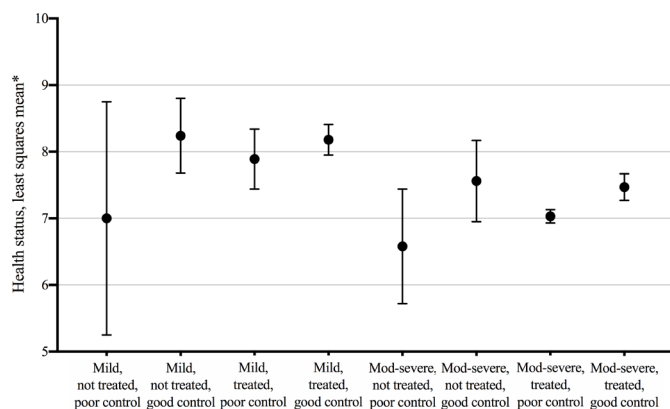


Figure 5 Parent-perceived burden: interaction between AR classification, receipt of treatment and adequacy of symptom control in children with AR aged 6 to 15 years. *Health status was based on the single question, 'In general, how would you describe your child's health?',^{16 18} adapted to be answered on a 10 cm VAS (0= poor health and 10= good health). Mean score was derived from the cut-off criteria: VAS<2= very poor; 2≤VAS<4= poor; 4≤VAS<6= good; 6≤VAS<8= very good; 8≤VAS≤10= excellent. Statistically significant differences in health status between seven comparisons: treated and mild AR and good control versus treated and moderate-severe AR and good control ($p=0.0008$), treated and mild AR and good control versus treated and moderate-severe AR and poor control ($p<0.0001$), treated and mild AR and good control versus not-treated and moderate-severe AR and poor control ($p=0.0081$), treated and mild AR and poor control versus treated and moderate-severe AR and poor control ($p=0.0126$), not-treated and mild AR and good control versus treated and moderate-severe AR and poor control ($p=0.001$), not-treated and mild AR and good control versus not-treated and moderate-severe AR and poor control ($p=0.0181$), treated and moderate-severe AR and good control versus treated and moderate-severe AR and poor control ($p=0.0095$). AR, allergic rhinitis; Mod, moderate; VAS, visual analogue scale.

schoolwork and other activities (table 2). Between-group comparisons showed that, among all children with AR, these activities were affected in significantly more children who had poor symptom control (versus good symptom control), in those with moderate-to-severe symptoms (versus mild symptoms) and those who were currently treating their AR (versus not currently treating) (table 2). Having AR was also associated with a reduced duration of sleep (8 hours or less per night: AR 494/797 (62%) vs No AR 126/314 (40%), $p<0.05$), poorer sleep quality and higher rates of absenteeism (table 2).

Parents' knowledge and beliefs about AR

As part of the survey, parents were asked if their child ever had hay fever. These data were then compared with children classified as having AR (AR cases) based on the answers that the parents gave to the ISAAC questions¹⁵ later in the survey. AR was not always recognised by the parents: overall, a history of AR was not reported in 118/797 (15%) of the children who were classified as having AR based on the ISAAC questions. Most parents

(669/797; 84%) believed that AR could significantly impair well-being, but their understanding of causes was poor; 375/797 (47%) believed it could only be caused by a reaction to something in the air outdoors, 128/797 (16%) believed that it was caused by a virus and 112/797 (14%) believed that it was contagious. Parents who had sought advice from a healthcare professional had primarily received written or verbal information about available treatment options (274/797; 34%), administration approaches (dosing regimen (169/797, 21%), how to use (191/797, 24%) and side effects (191/797, 24%)). Few received information about the condition itself (117/797, 15%), and two-third (509/797, 64%) of parents indicated that they would benefit from having more information about AR.

DISCUSSION

This study has confirmed that having AR significantly impacts a child's life as reported by parents. Among Australian children, aged 6 to 15 years, having AR was associated with greater parent-perceived burden, lower health status, fewer days of being healthy and more days of being unhealthy (poor physical or emotional health). It significantly reduced the child's ability to perform schoolwork and other activities, was associated with children accomplishing less than they would usually have done at school or in other activities, and reduced the level of care taken when performing schoolwork and other activities. Absenteeism and the likelihood of having comorbidities were increased, while sleep duration and quality were reduced.

Parent-perceived burden was highest in children who were not treated, who also had moderate-severe AR and reported inadequate symptom control. Statistical modelling, undertaken to help better define what was contributing to this parent-reported burden, found the most important overall factor leading to a lower health status was inadequate symptom control. Despite the majority of children being treated, half had inadequate symptom control (VAS score of >5 on a 10 cm scale). Parents reported that a large proportion of children used their medication only after their symptoms had started or when symptoms were very bothersome. While this may reflect that the majority of treated children were classified as having intermittent AR (mild: 19.7%, moderate-severe: 71.2%), and reflects on-demand treatment approaches observed in adults with AR,²⁸ it does not account for optimal pharmacology. For example, oral antihistamines have a rapid onset of action (1 to 2 hours), while for intranasal corticosteroids (INCS) the onset of action is 7 to 12 hours and it can take up to 2 weeks for maximum benefit to be achieved.²⁹ Established guidelines support that use of INCS on an as-needed basis is less effective than continuous use.³⁰

In an attempt to determine the relationship between treatment and impact of AR, participants were asked to report on whether their child had used their allergy medication that day, while also reporting on how bothersome

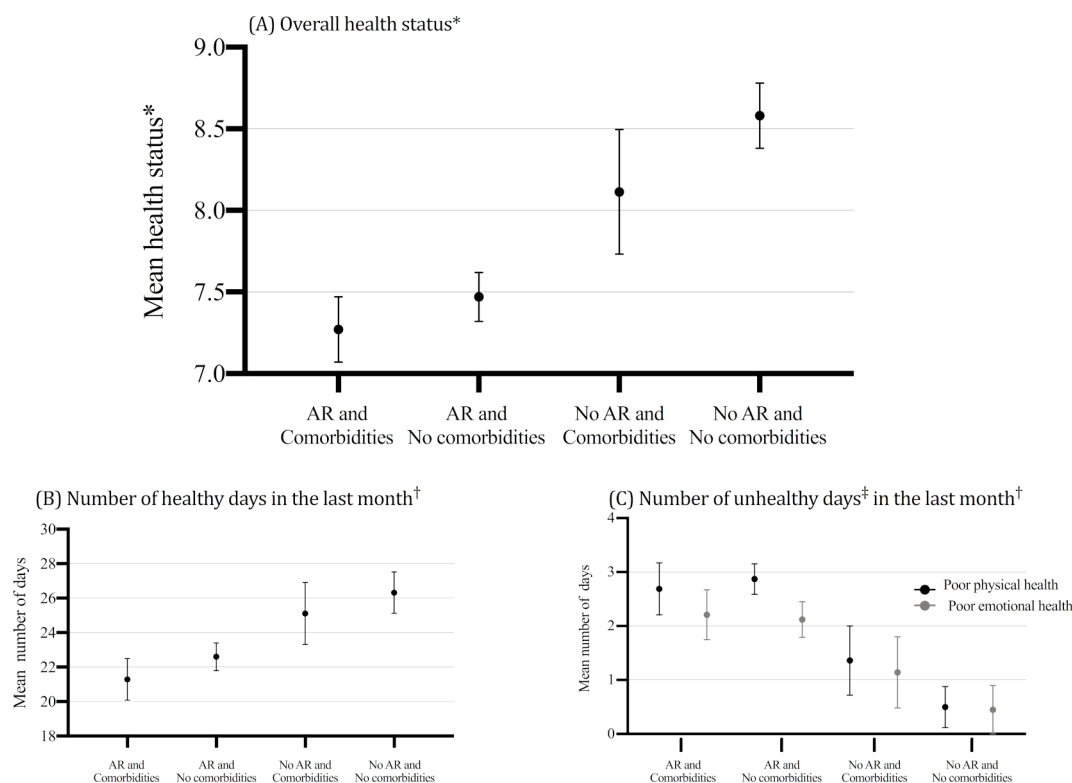


Figure 6 Parent-perceived burden: interaction between AR and comorbidities in children aged 6 to 15 years.*Health status was based on the single question, 'In general, how would you describe your child's health?',^{16 18} adapted to be answered on a 10 cm VAS (0= poor health and 10= good health). Mean score was derived from the cut-off criteria: VAS<2= very poor, 2≤VAS<4= poor, 4≤VAS<6= good, 6≤VAS<8= very good, and 8≤VAS≤10= excellent. †The number of days in the last month the child was healthy (happy and full of energy), had poor physical health and had poor emotional health were measured based on questions derived from the Centers for Disease Control and Prevention's Healthy Days Core Module¹⁷ and the Pediatric Allergies in America Survey¹⁸. ‡Unhealthy days=number of days of poor emotional health and number of days of poor physical health combined. (A) overall health status* (B) number of healthy days in the last month† (C) number of unhealthy days‡ in the last month†. AR, allergic rhinitis; VAS, visual analogue scale.

the AR symptoms were that day. The results were counter-intuitive to what would have been expected. AR symptoms were reported as being more bothersome in those children who had taken their medication that day compared with those who had not. While these data could be interpreted to mean that the medication taken had not worked, it is more likely (based on the order of the questions) that the children had been given medication because their symptoms had been bothersome that day. This is consistent with an approach of treating to alleviate the impact of AR, rather than based on disease severity. Community pharmacy research, conducted among Australian adults with AR has demonstrated that the majority (70%) self-select over-the-counter medications, but only 15% select an appropriate medication for their condition based on symptom severity.^{31 32} Symptom severity was found not to be a driving factor in medication choice, with patients reporting that they only sought advice from the pharmacist when they perceived their symptoms to be sufficiently bothersome to impact on their day-to-day lives.³³

This study has a number of limitations. The survey questionnaire was custom-designed for this research activity and was not validated in its entirety prior to use. However, it drew on a combination of validated tools and questions

previously used in similar surveys in paediatric AR. The term 'burden' was used to discuss the effect of AR on health and 'impact' to discuss its effect on activities of day-to-day living, such as schooling and sleep. The measures of burden are determined based largely on the CDC Healthy Days questionnaire¹⁷ and the measures of impact on questions in the Pediatric Allergies in America Study.¹⁸ Validity of the use of the single question to measure health status is supported in the literature¹⁶ and has previously been adapted and used in the AR setting to enable an adult to answer on behalf of a child in their care.¹⁸ Where possible, the survey questionnaire used VAS scales; thereby conforming to established, quantitative methods in other areas of AR research as a valid measure.^{34–36} The representativeness of the sample to that of the Australian population has been difficult to verify given the limited amount of participant demographic data collected. Based on the available data, the sample was slightly older, had a higher level of education and a higher household income than average Australians. This may have occurred due to the online nature of the survey methodology and may have introduced some bias, given that we found a higher household income was associated with an increased propensity to treat AR. The study was set up to collect parental perceptions rather than the

Table 2 Impact of AR on schoolwork and sleep quality in the past 4 weeks and absenteeism in the past 12 months									
	Cases (AR) versus Controls (No AR)	Cases (AR) treated versus not treated		Cases (AR)		Cases (AR)		Cases (AR)	
		Treated	Not treated	Poor control	Good control	Good versus poor symptom control	Mild versus moderate-severe	Mild	Moderate-severe
N	797	314	730	67	408	389	184	613	
Proportion of children who had difficulty performing schoolwork and other activities	445 (56%)*	53 (17%)	420 (58%)*	22 (33%)	297 (71%)*	152 (39%)	37 (20%)	405 (66%)*	
Proportion of children who accomplished less than they would usually have done at school or in other activities	419 (53%)*	44 (14%)	396 (54%)*	25 (37%)	286 (70%)*	136 (35%)	38 (21%)	383 (62%)*	
Proportion of children who took less care than usual when performing schoolwork and other activities	388 (47%)*	35 (11%)	368 (50%)*	23 (34%)	269 (66%)*	121 (31%)	31 (17%)	360 (59%)*	
Sleep quality: Proportion of children who:									
Woke up tired	367 (46%)*	72 (23%)	350 (48%)*	21 (31%)	212 (52%)*	156 (40%)	44 (24%)	325 (53%)*	
Had restless sleep	247 (31%)*	28 (9%)	226 (31%)	19 (28%)	159 (39%)*	89 (23%)	18 (10%)	233 (38%)*	
Had difficulty falling asleep	247 (31%)*	57 (18%)	234 (32%)	14 (21%)	135 (33%)	113 (29%)	39 (21%)	208 (34%)*	
Slept badly	151 (19%)*	19 (6%)	146 (20%)	5 (7%)	98 (24%)*	55 (14%)	8 (4%)	141 (23%)*	
Proportion of children who were absent from school at least once per month because they were unwell	255 (32%)*	35 (11%)	234 (32%)	17 (25%)	180 (44%)*	78 (20%)	18 (10%)	239 (39%)*	

*Between-group difference was statistically significant at 95% CI.
AR, allergic rhinitis.

views of children, this may have posed some limitations on the validity reliability of the data, due to proxy reporting bias, particularly in adolescents who were not given the opportunity to answer for themselves.

The PIAF study demonstrated the impact of parental asthma, eczema and AR on the odds of their offspring developing these conditions.¹³ Similarly, in our study, children with AR were significantly more likely to report a range of medical conditions (eg, asthma, cough, eczema, sinusitis and food allergy) in the family (parents/siblings and proband children) relative to children without AR. However, the survey questionnaire listed conditions for the respondents to select from, potentially introducing reporting bias, and there were no clinical examinations or objective tests to verify a diagnosis of AR, both of which limit the interpretation of the data.

In moving forward with the findings of this research, it is important to consider the implications in context with available AR management guidelines. ARIA guidelines developed over the past 20 years have incorporated evidence-based, integrated care approaches to AR management. Increased understanding of the importance of impact and adequacy of control to sufferers has led to a paradigm shift.³⁷ In recent years, the MACVIA-ARIA Sentinel Network has developed and validated VAS scales to evaluate the extent of AR symptom control.^{3 25} Well-controlled AR has previously been defined as a VAS of score of 2 or less.³⁸ The new ARIA guidelines for adults and adolescents recommend a step-up/step-down algorithm based on patient-report of symptom control assessed via a VAS, with a step-down if the score is <2, continuing as is for scores of ≥2 to <5, and stepping up if the score is ≥5.² The rationale being that better reflecting patients' needs and preferences will improve overall patient satisfaction and adherence, thereby optimising management. Given the availability of over-the-counter allergy medicines, and high levels of self-diagnosis and self-management of AR, the principles behind these guidelines and the use of VAS scales for self-assessment have been incorporated into care pathways, algorithms and shared decision support systems for use in the community pharmacy setting.^{37 39} A recent review of AR adds to this, supporting the view that shared decision-making can help to better equip patients to make appropriate decisions for optimal disease control.⁴⁰

Prior research has demonstrated that children with AR as young as 8 years of age are able to use self-assessment questionnaires, including VAS scales to report measures of disease severity and impact.⁴¹ The availability of app-based self-assessment tools, such as the MASK-Air Allergy Diary, opens up the concept that some children may be able to take a more active role in documenting the impact of the AR, providing opportunities to enhance shared decision making.

CONCLUSION

The parent-perceived burden of AR in Australian children aged 6 to 15 years is high and impacts many areas of

day-to-day living, including emotional well-being, physical health, school and sleep. Inadequate symptom control is a key driver of the extent of that impact. Parents have many misconceptions about AR and its management. Opportunities to optimise the management of AR in children include parental education, regular review and adoption of self-assessment tools to gauge and monitor adequacy of symptom control.

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Acknowledgements The authors would like to thank Dr Pascal Bourgeat for his input into the study design and statistical analysis plan, who passed away before the completion of the study fieldwork. Professional writing assistance in the preparation of this manuscript was provided by Hazel Palmer of Scriptix, and statistical analyses were performed by Erika Graetz of Ipsos. Both were funded by Sanofi Aventis Healthcare, Australia.

Contributors The following provides a summary of the contributions of each of the authors: SB-A, PS, MA, CMH, DBP, MJ and RS conceived the concept of this work and designed the study. SBA conceived the initial survey questions upon which this research is based. PS, MA, CMH, DBP, MJ and RS further refined the survey questions prior to ethics review and approval. SB-A, PS, DBP, MA and CMH were involved in the conduct of the study; data collection was undertaken by Ipsos. SB-A, PS, MA, CMH, DBP, MJ and RS directed the analysis of the data. SB-A, PS, MA, CMH, DBP, MJ and RS contributed to the interpretation of the results. SB-A, PS, MA, CMH, DBP, MJ and RS contributed to an outline from which the manuscript was drafted. SB-A, PS, MA, CMH, DBP, MJ and RS revised the manuscript critically for important intellectual content and gave final approval to the version to be published. SB-A accepts full responsibility for this work, had access to the data and controlled the decision to publish.

Funding This study was sponsored by Sanofi Aventis Healthcare, Australia, (Study Number DIREGL09198), which had input into the concept, study design, data analyses, data interpretation and preparation of this report. The study sponsor markets fexofenadine (Telfast). SBA, PS, DP, MJA and CH received honoraria from Sanofi Aventis Healthcare, Australia, for their involvement in an initial working group to determine the parameters of this research project. The authors were responsible for all content, the interpretation of the data and the decision to publish the results; they received no honoraria related to the development of this manuscript. The sponsor funded statistical and editorial assistance and reviewed the final draft before submission. Statistical analyses were performed externally (Erika Graetz of Ipsos). Editorial assistance in the preparation of this manuscript was provided by Hazel Palmer of Scriptix.

Competing interests All authors have completed the International Committee of Medical Journal Editors (ICMJE) uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: SB-A reports personal fees, non-financial support and other support from Sanofi Aventis Healthcare, Australia, during the conduct of the study, grants and personal fees from Teva, personal fees from AstraZeneca, personal fees from Boehringer Ingelheim, personal fees from GlaxoSmithKline, personal fees from Sanofi, and grants and personal fees from Mylan outside the

submitted work. PS reports personal fees and non-financial support from Sanofi Aventis Healthcare, Australia, during the conduct of the study, grants and personal fees from Meda, personal fees from Glaxo Smith Kline, and personal fees and other from Astra Zeneca outside the submitted work. DBP reports personal fees and non-financial support from Sanofi Aventis Healthcare, Australia, during the conduct of the study, personal fees from Amgen, grants and personal fees from Astra Zeneca, grants and personal fees from Boehringer Ingelheim, grants and personal fees from Chiesi, grants and personal fees from Circassia, personal fees from Cipla, personal fees from Glaxo Smith Kline, personal fees from Kyorin, grants and personal fees from Mylan, grants and personal fees from Mundipharma, grants and personal fees from Novartis, grants and personal fees from Pfizer, grants and personal fees from Regeneron Pharmaceuticals, grants from Respiratory Effectiveness Group, grants and personal fees from Sanofi Genzyme, grants and personal fees from Teva, grants and personal fees from Theravance, personal fees from Thermo Fisher, grants from UK National Health Service, non-financial support from Efficacy and Evaluation Mechanism Programme, and non-financial support from Health Technology Assessment, outside the submitted work; and stock/stock options from AKL Research and Development which produces phytopharmaceuticals; and owns 74% of the social enterprise Optimum Patient Care (Australia and UK) and 74% of Observational and Pragmatic Research Institute (Singapore). MA reports personal fees, non-financial and other support from Sanofi Aventis Healthcare, Australia, during the conduct of the study, grants from Pfizer, grants from Boehringer-Ingelheim, and personal fees from GlaxoSmithKline, outside the submitted work. CMH reports personal fees and non-financial support from Sanofi Aventis Healthcare, Australia, during the conduct of the study, grants from Amgen, other from Glaxo Smith Kline, and other from Pfizer outside the submitted work. MJ is an employee of Sanofi, Australia, reports personal fees from Sanofi, Australia, both during the conduct of the study and outside the submitted work. RS was an employee of Sanofi Aventis Healthcare, Australia, at the time this work was carried out and reports personal fees from Sanofi Aventis Healthcare, Australia, both during the conduct of the study and outside the submitted work.

Patient consent for publication Not required.

Ethics approval Bellberry Human Research Ethics Committee (Eastwood, South Australia, Australia) approved the study.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement Extra data is available upon reasonable request and with permission of Sanofi Australia Pty Ltd by emailing sinthia.bosnic-anticevich@sydney.edu.au. There are no plans to disseminate the results to the study participants.

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SURVEY QUESTIONNAIRE

STUDY NUMBER: DIREGL09198
STUDY NAME: Paediatric Allergic Rhinitis in Australia

QUESTIONNAIRE

Parental Perceptions of Childhood Allergic Rhinitis in Australia:
Understanding the Impact and Identifying Opportunities for Optimised Care

Version Number:	Final 3.0		
Date:	02-Oct-2018	Total number of pages:	20

Study Number: DIREGL09198
Date: 02-Oct-2018
Version Number: Final 3.0
Page 1 of 20

SURVEY QUESTIONNAIRE

SURVEY QUESTIONS

All questions will be asked of parents/guardians, who will answer on behalf of their child aged 2-15 years.

NOTES:

Throughout this document the term “child/children” refers to a child or ward of the adult who is answering the survey questions.

Text in red is instructional text and will not be seen by the participant.

A. INCLUSION CRITERIA

1	What is your gender?	Male Female	
2	In what year were you born (enter your response as a 4-digit number; e.g. 2018)?		If <21 years: Exit survey
3	How many children between the age of 2 and 15 years, for whom you are the parent or guardian, live in your household?		If none: Exit survey

SEEK INFORMED CONSENT TO CONTINUE WITH SURVEY**B. PARTICIPANT DEMOGRAPHY**

1	What is your highest completed educational qualification?	Less than Year 12 or equivalent Year 12 or equivalent (HSC/Leaving certificate) Vocational Qualification Bachelor degree Masters degree Doctorate Rather not say	
2	Which of the following best describes the area you live in?	Urban/capital city Regional Rural	
3	Please indicate your current annual (yearly) pre-tax household income	Under \$10,000 \$10,000-\$49,999 \$50,000-\$74,999 \$75,000-\$99,999 Over \$100,000 Rather not say	
4	We would like to find out the age and gender for each child between the age of 2 and 15 years in your household for whom you are the parent or guardian. For each child, please enter their age and gender.	Child 1: Age (years): Male/Female Child 2: Age (years): Male/Female	Enable sufficient rows for the number of children identified in QA3.

C. SCREENING [Case/Control group allocation] [Based on ISAAC questions^[1]]

Now thinking specifically about your [AGE AND

Applies only

Study Number: DIREGL09198

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SURVEY QUESTIONNAIRE

GENDER OF CHILD; e.g. son aged 12 years]			if >1 eligible child
1	Has your child ever had a problem with sneezing, or a runny, or blocked nose when he/she DID NOT have a cold or the flu?	Yes No	If no, skip to Q 6
2	In the past 12 months, has your child ever had a problem with sneezing, or a runny, or blocked nose when he/she DID NOT have a cold or the flu?	Yes No	If no, skip to Q 6
3	In the past 12 months, has this nose problem been accompanied by itchy-watery eyes?	Yes No	
4	In which of the past 12 months, did this nose problem occur? (Please select all that apply)	January February March April May June July August September October November December	
5	In the past 12 months, how much did this nose problem interfere with your child's daily activities?	Not at all A little A moderate amount A lot	
6	Has your child ever had hayfever?	Yes No	

D. FAMILY MEDICAL HISTORY & IMPACT [Some questions developed based on information in Zicari, 2013 ^[2]]

1	Have you ever been told by a doctor (diagnosed) that you have any of the following conditions? (Please select all that apply)	Asthma Sinusitis Hayfever/allergic rhinitis (nasal and/or eye allergy symptoms) Sleep disturbances Adenoids/tonsils hypertrophy Eczema (atopic dermatitis) Cough Recurrent wheezing Snoring Nasal polyps Hives (urticaria) Food allergy Oral allergy syndrome Recurrent respiratory infections Dental malocclusion None of the above	
2	Excluding the child that you are answering this survey about, have you been told by a doctor (diagnosed) that any of your other children aged 2-15 years have any of the following conditions? (Please select all that apply)	Asthma Sinusitis Hayfever/allergic rhinitis (nasal and/or eye allergy symptoms) Sleep disturbances Adenoids/tonsils hypertrophy	Applies only if >1 eligible child

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SURVEY QUESTIONNAIRE

		Eczema (atopic dermatitis) Cough Recurrent wheezing Snoring Nasal polyps Hives (urticaria) Food allergy Oral allergy syndrome Recurrent respiratory infections Dental malocclusion None of the above	
	Now thinking specifically about your [AGE AND GENDER OF CHILD; e.g. son aged 12 years]		Applies only if >1 eligible child
3	Has this child ever been told by a doctor (diagnosed) with any of the following conditions? (Please select all that apply)	Asthma Sinusitis Hayfever/allergic rhinitis (nasal and/or eye allergy symptoms) Sleep disturbances Adenoids/tonsils hypertrophy Eczema (atopic dermatitis) Cough Recurrent wheezing Snoring Nasal polyps Hives (urticaria) Food allergy Oral allergy syndrome Recurrent respiratory infections Dental malocclusion None of the above	
4	Has this child ever had or likely to have any of the following procedures? (Please select all that apply)	Tonsils removed Adenoids removed Tubes put in his/her ears Nasal or sinus surgery Required braces for their teeth None of the above	
5	During the past 12 months, how many times have you had to visit a doctor because your child was unwell?	0 1 2 3 4 5 6 7 8 9 10+	
6	What was the reason for this visit to the doctor? (Please select all that apply)	Asthma Sinusitis	Use “these visits” [if

Study Number: DIREGL09198

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SURVEY QUESTIONNAIRE

		Hayfever/allergic rhinitis (nasal and/or eye allergy symptoms)	more than one in Q prior]
		Sleep disturbances	
		Adenoids/tonsils hypertrophy	
		Eczema (atopic dermatitis)	
		Vaccinations	
		Cough	
		Nasal polyps	
		Hives (urticaria)	
		Respiratory tract infection	
		Urinary tract infection	
		Acne	
		Other	
7	During the past 12 months, how many days have you had to take off from work to care for your child because he/she was unwell?	0 1 2 3 4 5 6 7 8 9 10+	

E. HEALTH-RELATED QOL [Questions in Meltzer 2009^[3]; Meltzer, 2017^[4], information in Blaiss, 2018^[5]]

1	Using the scale below, in general how would you describe your child's health? VAS SCALE: 0-10 cm (0 = very poor, as bad as it can get, 10 = excellent, as good as it can get)		Single question supported by literature. ^[6]
2	During the past 30 days, for about how many days has your child appeared happy and full of energy?	Number of days None Don't know/not sure	Adding up the total in a 30-day period can be used to determine the number of normal days versus days affected by poor physical and/or emotional health. ^[7]
3	During the past 30 days, for about how many days has poor physical health kept your child from doing their usual everyday activities?	Number of days None Don't know/not sure	
4	During the past 30 days, for about how many days has poor emotional health kept your child from doing their usual everyday activities?	Number of days None Don't know/not sure	
5	During the past 4 weeks, has your child had difficulty in performing schoolwork or other activities because of his or her health?	Yes – schoolwork only Yes – other activities only Yes – schoolwork and other activities No	
6	During the past 4 weeks, has your child accomplished less than he or she would usually have done at school or in other activities because of his or her health?	Yes – school only Yes – other activities only Yes – school and other activities No	

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7	During the past 4 weeks, has your child done schoolwork or other activities less carefully than they usually would because of his or her health?	Yes – school only Yes – other activities only Yes – school and other activities No
8	During the past 4 weeks, how many hours of sleep a night has your child usually had?	6 or less 7 8 9 10 or more
9	During the past 4 weeks, has your child had any of the following? (please select all that apply)	Difficulty falling asleep Difficulty staying asleep Night-waking Sleeping badly Restless sleep Snoring Mouth breathing Waking up tired Daytime sleepiness None of the above
10	During the past 12 months, how often has your child needed to take time off school because he/she was unwell?	Once a week Once a month Once a term Once a semester Once a year Did not need to take time off

F. BELIEFS ABOUT MEDICINES [Questions from Smith, 2012^[8], based on the Beliefs about medicines questionnaire (BMQ) Horne, Weinman, Hankins, (1999) *Psychology and Health*, 14, 1-24]

1	Using the scale below, please indicate the extent to which you agree or disagree with the following statements:	Strongly agree Agree Uncertain Disagree Strongly disagree
	1. Doctors use too many medicines	
	2. People who take medicines should stop their treatment for a while every now and again	
	3. Most medicines are addictive	
	4. Natural remedies are safer than medicines	
	5. Medicines do more harm than good	
	6. All medicines are poisons	
	7. Doctors place too much trust on medicines	
	8. If doctors had more time with patients they would prescribe fewer medicines	

G. ALLERGIES KNOWLEDGE & BELIEFS [Questions derived from the recent literature of the knowledge, attitude and practice [KAP] questions in AR and asthma, e.g. Alreshidi, 2017; Rajasekaran, 2018 and Zhao, 2013^[9-11]

1	Using the scale below, please indicate the extent to which you agree or disagree with the following statements:	Strongly agree Agree Uncertain Disagree Strongly disagree
	1. Hayfever/allergic rhinitis is contagious	

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2. Hayfever/allergic rhinitis is caused by a virus
3. Hayfever/allergic rhinitis can be prevented
4. Hayfever/allergic rhinitis is linked to asthma and conjunctivitis
5. Hayfever/allergic rhinitis runs in families
6. Having Hayfever/allergic rhinitis can significantly impact on a person's well-being
7. Hayfever/allergic rhinitis can only be caused by a reaction to something in the air outdoors
8. Hayfever/allergic rhinitis can only be diagnosed by a specialist

<<CASE CHILDREN ONLY FROM HERE>>

H. CLASSIFICATION OF AR [ARIA classification allocation] [Based on ARIA Criteria ^[12] ^[13]]

Now thinking specifically about your [AGE AND GENDER OF CHILD; e.g. son aged 12 years]			Applies only if >1 eligible child
1	In a typical week, on how many days is your child affected by their hayfever/allergic rhinitis (nasal and/or eye allergy)?	1-3 days a week 4 or more days a week	
2	In a typical month, how many weeks is your child affected by their hayfever/allergic rhinitis (nasal and/or eye allergy)?	1-3 weeks Every week	
3	Does your child's hayfever/allergic rhinitis (nasal and/or eye allergy): <ul style="list-style-type: none"> o Disturb their sleep o Restrict their daily activities like sports and leisure o Restrict their participation in school Is your child's hayfever/allergic rhinitis (nasal and/or eye allergy symptoms) troublesome?	Yes/No Yes/No Yes/No Yes/No	All no = mild; 1 or more yes = moderate-severe.

I CONTROL OF AR [based on recent symptom control]

1	Using the scale below, and thinking about the last 2 weeks, overall how bothersome have your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms been? VAS SCALE: 0-10 cm 0 cm = not at all bothersome 10 cm = extremely bothersome (as bad as they can get)	A cut off of 5 cm will be used to discriminate between recent good symptom control and inadequate symptom control. ^[14]
---	--	--

J. AR SYMPTOMS [Based on ^[12], ^[13], ^[15]; Questions in Meltzer 2009 ^[3] Meltzer, 2017^[4]]

1	When your child has hayfever/allergic rhinitis (nasal and/or eye allergy), which of these symptoms does your child have? (Please select all that apply)	Nasal symptoms: Runny nose Itchy nose Nasal congestion Repeated sneezing
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		<u>Eye symptoms:</u> Red eyes Itchy eyes Watering eyes <u>Bronchial symptoms:</u> Dry cough Snoring <u>Other:</u> Irritable Easily distracted Difficulty getting to sleep Disturbed sleep Headaches/sinus pain Facial pain Ear pain Difficulty hearing	
2	Using the scale below, how bothersome are your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? VAS SCALE: 0-10 cm 0 cm = not at all bothersome 10 cm = extremely bothersome (as bad as they can get)	<u>Nasal symptoms:</u> Runny nose Itchy nose Nasal congestion Repeated sneezing <u>Eye symptoms:</u> Red, itchy eyes Watering eyes <u>Bronchial symptoms:</u> Dry cough Snoring <u>Other:</u> Irritable Easily distracted Difficulty getting to sleep Disturbed sleep Headaches/sinus pain Facial pain Ear pain Difficulty hearing	[Pre-fill so that they answer only for the symptoms previously selected at Q J1] 5 cm cut off to discriminate between mild and moderate/severe. ^[15]
3	What is the most bothersome hayfever/allergic rhinitis (nasal and/or eye allergy) symptom that your child seeks treatment for? (Select one only)	<u>Nasal symptoms:</u> Runny nose Itchy nose Nasal congestion Repeated sneezing <u>Eye symptoms:</u> Red, itchy eyes Watering eyes <u>Bronchial symptoms:</u> Dry cough Snoring <u>Other:</u>	[Pre-fill so that they answer only for the symptoms previously selected at Q J1]

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		Irritable Easily distracted Difficulty getting to sleep Disturbed sleep Headaches/sinus pain Facial pain Ear pain Difficulty hearing	
4	Which of the following words, if any, describe how your child feels when suffering from hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Angry Unhappy Distracted Having poor concentration Embarrassed Frustrated Irritable Tired Upset Unattractive Unproductive/having reduced productivity Unable to perform at his or her best Less confident Indifferent/don't care None of these	
5	During what time of the day are your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms worse?	Morning Afternoon Evening Bedtime No time is worse	Multiple responses will be possible for all, but not for "no time is worse"
6	Using the scale below, how much do your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms interfere with each of the following:	Sleep Leisure/sport activities Participation at school	
VAS SCALE: 0-10 cm (0 = not at all, 10 = a lot)			

K. AR DIAGNOSIS [Questions in Meltzer, 2017^[4], and some questions developed based on information in Baena-Cagnani, 2015^[16]

1	How old was your child when he/she first started having these hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms?	
2	Who made the diagnosis of hayfever/allergic rhinitis (nasal and/or eye allergy)? (Please select all that apply)	General Practitioner Allergy specialist Clinical immunologist Ear, nose and throat specialist Paediatrician Pharmacist Nurse Dietician Herbalist Naturopath

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		Myself Other None
3	Which, if any, of the following providers have you seen about your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	General Practitioner Allergy specialist Clinical immunologist Ear, nose and throat specialist Paediatrician Pharmacist Nurse Dietician Herbalist Naturopath Other None
4	Who else have you sought advice from about your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Family members Friends Other parents Internet Other None
5	What types of information have you received from a healthcare provider (specialist, doctor, pharmacist) about your hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	<u>Written information about:</u> The disease Available treatment options Treatment expectations Dosing regimen Medicine side effects How to administer treatments How to use an inhaler Other aspects <u>Verbal information about:</u> The disease Available treatment options Treatment expectations Dosing regimen Medicine side effects How to administer treatments How to use an inhaler None
6	Using the scale below, do you think you would benefit from more information on what hayfever/allergic rhinitis (nasal and/or eye allergy) is and how it is managed? 0 = not at all 1 = a little bit 2 = it might help	[Adapted from CENSA Questionnaire (submitted manuscript)]

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 3 = it would be very useful

L. AR TRIGGERS & TESTING [Questions in Meltzer, 2017^[4] and some questions developed based on information in Zicari, 2013^[2]]

1	Has your child ever been given a skin test to see what he/she was allergic to?	Yes/no
2	If yes, who carried out this skin test?	General Practitioner Allergy specialist Clinical immunologist Ear, nose and throat specialist Paediatrician Herbalist Naturopath Other
3	Has your child ever been given a blood test to see what he/she was allergic to?	Yes/no
4	If yes, who carried out this blood test?	General Practitioner Allergy specialist Clinical Immunologist Ear, nose and throat specialist Paediatrician Herbalist Naturopath Other
5	What kinds of things trigger your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Grass pollen Tree pollen Weed pollen Mold spores House dust mites Animal dander (e.g. dead skin cells and hair or feathers) Foods Other allergens Do not know

M. AR MANAGEMENT/SYMPTOM CONTROL [Questions in Meltzer 2009^[3]; Meltzer, 2017^[4]]

1A	Which of the following types(s) of allergy medicines has your child <i>ever tried</i> using to manage his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Tablets/liquids Nasal sprays Eye drops Other None Don't know
1B	Which of the following allergy medicines has your child <i>ever tried</i> using to manage his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Tablets/liquids: Oral non-sedating antihistamines Oral sedating antihistamines Oral decongestants Oral corticosteroids Oral combination products

[Show only those categories that were selected in 1A. Include names and

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		Leukotriene receptor antagonists <u>Nasal sprays:</u> Antihistamine nasal sprays Decongestants nasal sprays Corticosteroid nasal sprays Combination nasal sprays Anticholinergic nasal spray Intranasal mast cell stabilisers Nasal saline spray <u>Eye drops:</u> Antihistamine eye drops Other eye drops <u>Other:</u> Allergen immunotherapy (“shots”) Vitamins Herbal supplements None Don’t know	images of brands to aid with recognition, see list in appendix to this document]
2A	Which of the following types(s) of allergy medicines is your child <i>currently using</i> to manage his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	Tablets/liquids Nasal sprays Eye drops Other None Don’t know	
2B	Which of the following allergy medicines is your child <i>currently</i> using to manage his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? (Please select all that apply)	<u>Tablets/liquids:</u> Oral non-sedating antihistamines Oral sedating antihistamines Oral decongestants Oral corticosteroids Oral combination products Leukotriene receptor antagonists <u>Nasal sprays:</u> Antihistamine nasal sprays Decongestants nasal sprays Corticosteroid nasal sprays Combination nasal sprays Anticholinergic nasal spray Intranasal mast cell stabilisers Nasal saline spray <u>Eye drops:</u> Antihistamine eye drops Other eye drops	[Show only those categories that were selected in 2A. Include names and images of brands to aid with recognition, see list in appendix to this document]

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		<u>Other:</u> Allergen immunotherapy ("shots") Vitamins Herbal supplements None Don't know	
3	Does your child ever need to use more than one type of medicine at the same time?	Yes No	
	If yes, which of the following combinations do they use?	Antihistamine + decongestant Antihistamine + intranasal steroid Other	
4	Using the scale below, how bothersome would you say each of the following hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms is when your child has NOT taken his/her allergy medication? VAS SCALE: 0-10 cm (0 = not at all bothersome, 10 = very bothersome)	<u>Nasal symptoms:</u> Runny nose Itchy nose Nasal congestion Repeated sneezing <u>Eye symptoms:</u> Red, itchy eyes Watering eyes <u>Bronchial symptoms:</u> Dry cough Snoring <u>Other:</u> Irritable Easily distracted Difficulty getting to sleep Disturbed sleep Headaches/sinus pain Facial pain Ear pain Difficulty hearing	[Pre-fill so that they answer only for the symptoms previously selected at Q J1] MACVIA ARIA defined AR control cut-offs are: >50: uncontrolled, 20–50: partly controlled, <20: well controlled. ^[17]
5	Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, who advised your child to take this medicine? (Select one only)	Specialist Doctor Pharmacist Nurse No one Myself Family or friend	
6	Using the scale below, please indicate the extent to which you agree or disagree with the following statements: 1. My child's health at present depends on their allergy medicines 2. My child having to take allergy medication worries me 3. My child's life would be impossible without my allergy medication	Strongly agree Agree Uncertain Disagree Strongly disagree	[Adapted from BMQ-Specific ^[8]]

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<p>4. Without his/her allergy medication my child would be very ill</p> <p>5. I sometimes worry about the long term effects of my child's allergy medication</p> <p>6. My child's allergy medication is mystery to me</p> <p>7. My child's health in the future will depend on his/her allergy medication</p> <p>8. My child's allergy medication disrupts his/her life</p> <p>9. I sometimes worry about my child becoming too dependent on his/her allergy medication</p> <p>My child's allergy medication protects him/her from becoming worse</p>	<p>7</p>	<p>Using the scale below and thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, how important is it to you that your child takes this medicine in the exact way it is recommended (e.g. per the labelled instructions)?</p>	<p>1 = not at all important 2 = not very important 3 = somewhat important 4 = very important</p>	<p>[Adapted from CENSA Questionnaire (submitted manuscript)]</p>
<p>8</p> <p>Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, which statement best describes when they usually take their medication? (Please select only one answer for each medicine used)</p>	<p>8</p>	<p>Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, which statement best describes when they usually take their medication? (Please select only one answer for each medicine used)</p>	<p>Takes it all year-round Takes it before the allergy season starts Takes it only during the allergy season Takes it only after symptoms have started Takes it only when symptoms are very bothersome Does not take it</p>	<p>[Answer the same Q for all those previously selected as currently using at Q M2.]</p>
<p>9</p> <p>Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, which statement best describes how often they take their medication? (Please select only one answer for each medicine used)</p>	<p>9</p>	<p>Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, which statement best describes how often they take their medication? (Please select only one answer for each medicine used)</p>	<p>Once a month Once a week Once a day Twice a day Three times a day Only when symptoms are present Only when symptoms are very bothersome Does not take it</p>	<p>[Answer the same Q for all those previously selected as currently using at Q M2.]</p>
<p>10</p> <p>Has your child used their allergy medication(s) today?</p>	<p>10</p>	<p>Has your child used their allergy medication(s) today?</p>	<p>Yes No</p>	<p>•</p>

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11	Using the scale below, how bothersome are your child's hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms today? VAS SCALE: 0-10 cm (0 = not at all bothersome, 10 = very bothersome)		MACVIA ARIA defined AR control cut-offs are: <ul style="list-style-type: none"> • >50: uncontrolled, • 20–50: partly controlled, • <20: well controlled.^[17]
12	Using the scale below, how satisfied are you with the effectiveness of each of the following types of medication your child uses to relieve his/ hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms? 0 = does not use this medication 1 = not at all satisfied 2 = somewhat satisfied 3 = satisfied 4 = very satisfied 5 = extremely satisfied	<u>Tablets/liquids:</u> Oral non-sedating antihistamines Oral sedating antihistamines Oral decongestants Oral corticosteroids Oral combination products Leukotriene receptor antagonists <u>Nasal sprays:</u> Antihistamine nasal sprays Decongestants nasal sprays Corticosteroid nasal sprays Combination nasal sprays Intranasal mast cell stabilisers Nasal saline spray <u>Eye drops:</u> Antihistamine eye drops Other eye drops <u>Other:</u> Allergen immunotherapy ("shots") Vitamins Herbal supplements	[Answer the same Q for all those previously selected as currently using at Q M2. We will drop in names and/or images of brands for them to select to aid with this]
[IPSOS Please Note: For those children who are taking a Sanofi product AND who respond to the above question with options 1 or 2, this would be reportable to Sanofi Product Safety as PV Data (lack of efficacy)]			
13	Thinking about the medication(s) that your child currently uses to relieve his/her hayfever/allergic rhinitis (nasal and/or eye allergy) symptoms, how would you describe your child's ability to always take that medicine in the exact way it is recommended (e.g. per the labelled instructions)?	Excellent Very good Good Poor Very poor Don't know	Answer the same Q for all those previously selected as currently using at Q M2. Based on

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self-rating
scale item
(SRSI) is a
single-item
self-report
adherence
measure
[Feldman,
2013]^[18]

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Medicine descriptions for use for use at Q's M1A and B, 2A and B, 8, 9, 11 and 12:

Category	Medicine type	Active ingredient	Example of brand
Tablets/liquids	Oral non-sedating antihistamines	• Cetirizine	Little Allergies for Children, Alzene, Zilarex, Zyrtec, Zodac, ZepAllergy, Cetrelief
		• Desloratadine	Aerius
		• Fexofenadine	Allerfexo, Telfast, Amcal Fexo, Chemist's Own Fexo, Fexal, Fexotabs, Guardian Fexo, Tefodine, Xergic, Pharmacy Action Fexorelief
		• Levocetirizine	Xyzal
	Oral sedating antihistamines	• Loratadine	Claratyne, Amcal Loratadine, Chemist's Own loratadine, Guardian Loratadine, Alledine, Allergydyne, Allereze, Lorano
		• Cyproheptadine	Periactin
		• Dexchlorpheniramine	Polaramine
		• Diphenhydramine	Children's Paedamin Antihistamine
	Oral decongestants	• Pheniramine	Avil
		• Promethazine	Allersoothe, Phenergan
		• Pseudoephedrine	Sudafed
		• Prednisone	Panfacort
	Oral combination products	• Pseudoephedrine + fexofenadine	Telfast decongestant
		• Pseudoephedrine + loratadine	Claratyne-D
	Leukotriene receptor antagonists	• Montelukast	Singulair, Lukair
		• Zafirlukast	Accolate

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<u>Nasal sprays:</u>			
Antihistamine nasal sprays	• Azelastine	Azep	
	• Levocabastine	Livostin nasal spray	
Decongestant nasal sprays	• Oxymetazoline	Chemists' Own Decongestant Nasal Spray, Demazin 12 Hour Relief Nasal Spray, Dimetapp 12 Hour Nasal Spray, Drixine, Logicin Rapid Relief Nasal Spray, Pharmacy Action Nasal decongestant Spray, Vicks Sinex	
	• Xylometazoline	FLO Xylo-POS Nasal Spray, Otrivin Nasal Spray, Otrivin Junior, Otrivin Menthol, Otrivin Plus	
	• Tramazoline	Spray-Tish Menthol, Spray-Tish	
Corticosteroid nasal sprays	• Beclomethasone	Beconase	
	• Budesonide	Rhinocort Hayfever, Rhinocort, Budamax	
	• Ciclesonide	Omnaris	
	• Fluticasone	Avamys, Flixonase	
	• Mometasone	Nasonex, Sensease Nasal Allergy Relief, Chemmart Mometasone Nasal Spray, Terry White Chemists Mometasone Nasal Spray, APO Mometasone Nasal Spray	
	• Triamcinolone	Telnase	
Combination nasal sprays	• Azelastine + fluticasone	Dymista	
Anticholinergic nasal spray	• Ipratropium bromide	Atrovent Nasal	
Intranasal mast cell stabilisers	• Sodium cromoglycate	Rynacrom	
Nasal saline spray	• Sodium chloride	Fess, Flo, Flo Kids, PediaMist	
<u>Eye drops:</u>		• Sodium cromoglycate	Cromolux eye drops, Opticrom eye drops
		• Lodoximide	Lomide eye drops

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	<ul style="list-style-type: none">• Antazoline + naphazoline	Albolon-A eye drops, Antistine-Privine eye drops
	<ul style="list-style-type: none">• Azelastine	Eyezep eye drops
	<ul style="list-style-type: none">• Ketotifen	Zaditen eye drops
	<ul style="list-style-type: none">• Levocabastine	Livostin eye drops, Zyrtec Levocabastine eye drops
	<ul style="list-style-type: none">• Olopatadine	Patanol
Other:		
Allergen immunotherapy	<ul style="list-style-type: none">• Injections or “shots” given by a doctor	
Vitamins	<ul style="list-style-type: none">• Vitamin C	
	<ul style="list-style-type: none">• Vitamin C combination	Garlic, Vitamin C and horseradish
Herbal supplements	<ul style="list-style-type: none">• Herbal combination• Quercetin/bioflavonoids• MSM (methylsulfonylmethane)• Glutamine• Bromelain• Curcumin (turmeric)• Probiotics• Bee pollen extract• Propolis• Echinacea	Ki Hayfever Control Formula

Sourced from:
Smith P, Price D, Harvey R, et al. Medication-related costs of rhinitis in Australia: a NostraData cross-sectional study of pharmacy purchases. *Journal of Asthma and Allergy*. 2017;10:153-161.
<http://www.mydr.com.au/allergy/hay-fever-treatments>

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Study Number: DIREGL09198

Date: 02-Oct-2018

Version Number: Final 3.0

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Supplementary Tables

Adequacy of symptom control drives health-related quality of life in paediatric allergic rhinitis: Insights from an Australian cross-sectional study

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Supplementary Table S1. Respondent demographics

	Total N=1541	Cases (AR) N= 1040	Controls (No AR) N=501
Gender			
Male	528 (34.3%)	379 (36.4%)	149 (29.7%)
Female	1013 (65.7%)	661 (63.6%)	352 (70.3%)
Mean age (\pm SD), years	41.6 \pm 9.0	41.4 \pm 8.9	42.1 \pm 9.1
Family demographics			
Number of children aged 2-15			
1	718 (46.6%)	499 (48.0%)	219 (43.7%)
2	621 (40.3%)	428 (41.2%)	193 (38.5%)
3	156 (10.1%)	86 (8.3%)	70 (14.0%)
4	38 (2.5%)	24 (2.3%)	14 (2.8%)
5	8 (0.5%)	3 (0.3%)	5 (1.0%)
Gender of children:			
Male	771 (50.0%)	536 (51.5%)	235 (46.9%)
Female	770 (50.0%)	504 (48.5%)	266 (53.1%)
Mean age of children, years	8.9 \pm 4.3	9.4 \pm 4.2	7.9 \pm 4.3
Geographic location			
Urban/capital city	1079 (70.0%)	777 (74.7%)*	302 (60.3%)
Regional/Rural	462 (30.0%)	263 (25.3%)	199 (39.7%)
Education			
Less than Year 12 or equivalent	146 (9.5%)	88 (8.5%)	58 (11.6%)
Year 12 or equivalent (HSC/Leaving certificate)	233 (15.2%)	158 (15.2%)	75 (15.0%)
Vocational Qualification	409 (26.7%)	260 (25.0%)	149 (29.7%)
Bachelor degree	555 (36.2%)	382 (36.7%)*†	173 (34.5%)
Masters degree	163 (10.6%)	130 (12.5%)*†	33 (6.6%)
Doctorate	27 (1.8%)	17 (1.6%)*†	10 (2.0%)
Not specified	8 (0.5%)	5 (0.5%)	3 (0.6%)
Pre-tax household income			
Up to \$49,999	264 (17.1%)	163 (15.7%)	101 (20.2%)
\$50,000-\$74,999	269 (17.5%)	192 (18.5%)	77 (15.4%)
\$75,000-\$99,999	294 (19.1%)	206 (19.8%)	88 (17.6%)
Over \$100,000	600 (38.9%)	424 (40.8%)	176 (35.1%)
Not specified	114 (7.4%)	55 (5.3%)	59 (11.8%)

Note: The survey recruited consecutive, self-identified panel respondents until quotas were met. The quotas were stratified based on the age and gender of the child, and geographical location.

* Statistically significant association between location and presence of AR: higher in urban areas ($P < 0.0001$);

† When higher education levels are combined, statistically significant association between education and presence of AR: higher in more educated participants ($p < 0.005$), which may be a reflection of better recognition and/or access to medical care.

Supplementary Table S2. Symptoms experienced by children with AR.

Children aged 6-15 years		Cases (AR)	Cases (AR)
	Cases (AR)	Treated	Not treated
	N= 797	N= 730	N=67
Nasal symptoms:			
Runny nose	63%	66%	37%
Repeated sneezing	55%	56%	42%
Itchy nose	49%	51%	25%
Nasal congestion	43%	45%	24%
Eye symptoms:			
Itchy eyes	59%	62%	33%
Watering eyes	49%	51%	27%
Red eyes	30%	32%	7%
Bronchial/upper airway symptoms:			
Dry cough	30%	30%	30%
Snoring	22%	22%	15%
Other:			
Irritable	34%	35%	19%
Disturbed sleep	30%	32%	10%
Difficulty getting to sleep	25%	26%	6%
Headaches/sinus pain	26%	27%	18%
Easily distracted	16%	17%	12%
Ear pain	12%	12%	7%
Facial pain	8%	8%	4%
Difficulty hearing	6%	6%	7%

Green shading indicates a significant difference between respective AR Treated and AR Not Treated groups at 95% CI ($p < 0.05$).

Supplementary Table S3. Overall usage trends for different classes of medications* (most common time to use is highlighted).

Cases (AR) Treated N= 939*	N	Takes it all year-round	Takes it before the allergy season starts	Takes it only during the allergy season	Takes it only after symptoms have started	Takes it only when symptoms are very bothersome
Oral non-sedating antihistamines	422 (44.9%)	9%	7%	26%	39%	19%
Oral sedating antihistamines	81 (8.6%)	2%	7%	30%	31%	30%
Oral decongestants	77 (8.2%)	5%	9%	22%	43%	20%
Oral combination products	151 (16.1%)	5%	3%	33%	35%	23%
Antihistamine nasal sprays	110 (11.7%)	4%	9%	27%	45%	13%
Decongestants nasal sprays	128 (13.6%)	6%	9%	29%	37%	20%
Corticosteroid nasal sprays	147 (15.7%)	9%	8%	25%	38%	21%
Nasal saline spray	114 (12.2%)	15%	6%	21%	38%	19%
Antihistamine eye drops	124 (13.2%)	3%	3%	37%	43%	14%
Other eye drops	30 (3.2%)	0%	4%	27%	47%	23%

*More than one medicine category could be chosen per child.